REMARKS

Claims 80-84 and 87-102 are pending in the instant application. Claims 99-102 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants in this response. Claims 80-84 and 87-98 have been rejected. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Restriction Requirement

The Examiner has maintained the Restriction Requirement with respect to claims 99-102. Thus, in an earnest effort to advance the prosecution of this case, Applicants have canceled without prejudice these claims. Applicants reserve the right to file a divisional application to the canceled subject matter.

II. Objection to Specification under 35 U.S.C. 132

The Examiner has maintained, in part, the objection under 35 U.S.C. 132 to the August 6, 2004 amendments to the specification. The Examiner suggests that the August 6, 2004 amendment introduced new matter at page 12, line 14, page 24, line 12 and page 25, line 4. Specifically, the Examiner suggests that no explanation was provided as to why

the alteration from amino acids 20 to 199 to amino acids 20 to 192 and (SEQ ID NO:28) was made.

It is respectfully pointed out that the paragraph beginning at page 12, line 14 was amended in the reply filed March 28, 2005 to state 20 to 199 in accordance with the originally filed specification.

However, in an earnest effort to advance the prosecution of this case and to address all issues raised by the Examiner in this Office Action, Applicants have further amended this paragraph herein to remove reference to SEQ ID NO:28.

Applicants have similarly amended herein paragraphs beginning at page 24, line 12 and page 25, line 4.

Withdrawal of this objection to the specification is therefore respectfully requested.

III. Rejection of Claims 80, 81, 87, 88, 89, 90, 91, 92, 93, 94, 95 and 96 under 35 U.S.C. 102(a)

Claims 80, 81, 87, 88, 89, 90, 91, 92, 93, 94, 95 and 96 have been rejected under 35 U.S.C. 102(a) as being anticipated by Takahashi. The Examiner suggests that Takahashi et al. teach a two site enzyme immunoassay for skeletal fast twitch skeletal troponin I (p. 301, right column, 2nd paragraph, p. 302, whole page, p. 304, left

column), wherein the complex is detected by horseradish peroxidase (p. 303, left column, 2nd paragraph), wherein the skeletal muscle damage is reversible (hypoxia: marathon runners - see p. 304, right column, 3rd paragraph) or irreversible (chronic degenerative muscle disease - p.305, left column, last paragraph, wherein the biological sample is blood serum (p. 303, right column, 2nd paragraph; thus meeting all the limitations of claims 80, 87, 88, 89, 90, 91, 92, 93, 94, 95 and 96.

Applicants respectfully traverse this rejection.

As acknowledged by the Examiner at page 5-6 of the Office Action mailed June 19, 2006, the claims are drawn to a method for assessing skeletal muscle damage in subject, comprising detecting the presence or absence or measuring the amount of a **peptide fragment** of a myofilament protein. Further, as acknowledged by the Examiner, the claims state that the peptide fragment consists of a skeletal troponin I **peptide fragment**, a skeletal myosin light chain 1 **peptide fragment**, a skeletal troponin T **peptide fragment**, a skeletal troponin C **peptide fragment** or a skeletal α-actinin **peptide fragment**.

In contrast, Takahashi et al. teaches detection of **intact** fast-twitch skeletal TnI.

The fact that "peptide fragment" of a myofilament protein, as used in the instant claims, is not meant to be inclusive of an intact myofilament protein is made clear by the language of the claims. See for example, part (b) (i) and (ii) of claim 80 which state "a covalent or non-covalent complex of at least:

(i) a peptide fragment of a myofilament protein and an intact myofilament protein; or

(ii) two peptide fragments of myofilament proteins,"

. If "peptide fragment" of a myofilament protein was meant to be inclusive of intact myofilament proteins, the claims would not require both parts (i) and (ii).

Accordingly, Takahashi et al. which only teaches detection of an intact myofilament protein, in particular fast-twitch skeletal TnI, does not teach all the elements of the instant claimed invention and thus cannot anticipate the instant claimed invention. See MPEP 2131.

Withdrawal of this rejection under 35 U.S.C. 102(a) is therefore respectfully requested.

IV. Rejection of Claims 80-84 and 87-98 under 35 U.S.C. 103(a)

Claims 80-84 and 87-98 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi et al., as applied to claims 80, 81, 87, 88, 90, 91, 92, 93, 94, 95 and 96 in Section III, supra and further in view of Westfall

et al. The Examiner suggests that it would have been obvious to the person of ordinary skill in the art at the time of the invention to modify the teachings of Takahashi et al. by measuring more than one peptide fragment and comparing the extent of damage, as taught by Westfall et al. because according to Westfall et al. myocardial ischemia may cause changes in individual myofibrillar proteins that affect myofibrillar function thus suggesting that more than one protein should be measured to assess the full spectrum of damage.

Applicants respectfully traverse this rejection.

As discussed in Section III, supra, Takahashi et al. teaches detecting **intact** fast-twitch skeletal TnI, not detecting peptide fragments of a myofilament protein as claimed.

Further, Westfall et al. relates to cardiac muscle, not skeletal muscle, and thus is no way predictive of the claimed method for detecting skeletal muscle damage.

Thus, the cited combination of references provides neither the requisite teaching or suggestion of all the limitations of the claims nor any reasonable expectation of success with respect to the instant claimed invention to render obvious the instant claimed invention.

Withdrawal of this rejection under 35 U.S.C. 103(a) is therefore respectfully requested.

V. Provisional Obviousness-type Double Patenting

Claims 80-84 and 92-98 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 16-18, 20-28, 31, 34-35 and 37-41 of copending Application No. 09/419,901. The Examiner has acknowledged that the conflicting claims are not identical. However, the Examiner suggests that both are drawn to assessing skeletal muscle damage. Further, the Examiner suggests that the copending '901 claims recite "protein modification products", which read on cleaving signal sequences or other post-translational modifications.

Applicants respectfully traverse this rejection.

Claims of the instant application are drawn to methods for detecting a **peptide fragment** of a myofilament protein; or a covalent or non-covalent complex of at least a **peptide fragment** of a myofilament protein and an intact myofilament protein; or two **peptide fragments** of myofilament proteins. In contrast, claims of the copending '901 patent application are drawn to detecting a myofilament protein modification product wherein at least one myofilament protein modification product is a **chemical adduct** of a myofilament protein. Applicants believe that detection of these different products renders the instant claims patentably distinct from the pending claims of the '901 application.

Accordingly, reconsideration and withdrawal of this provisional obviousness-type double patenting rejection is respectfully requested.

VI. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

Kathleen A. Tyrrell
Registration No. 38,350

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Licata & Tyrrell P.C.
66 E. Main Street
Marlton, New Jersey 08053

(856) 810-1515